

§ 803.11

21 CFR Ch. I (4–1–08 Edition)

(1) Submit reports of individual adverse events no later than 10 work days after the day that you become aware of a reportable event:

(i) Submit reports of device-related deaths to us and to the manufacturer, if known; or

(ii) Submit reports of device-related serious injuries to the manufacturers or, if the manufacturer is unknown, submit reports to us.

(2) Submit annual reports (described in § 803.33) to us.

(b) If you are an importer, you must submit reports (described in subpart D of this part), as follows:

(1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable event:

(i) Submit reports of device-related deaths or serious injuries to us and to the manufacturer; or

(ii) Submit reports of device-related malfunctions to the manufacturer.

(2) [Reserved]

(c) If you are a manufacturer, you must submit reports (described in subpart E of this part) to us, as follows:

(1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable death, serious injury, or malfunction.

(2) Submit reports of individual adverse events no later than 5 work days after the day that you become aware of:

(i) A reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health, or

(ii) A reportable event for which we made a written request.

(3) Submit annual baseline reports.

(4) Submit supplemental reports if you obtain information that you did not submit in an initial report.

§ 803.11 What form should I use to submit reports of individual adverse events and where do I obtain these forms?

If you are a user facility, importer, or manufacturer, you must submit all reports of individual adverse events on FDA MEDWATCH Form 3500A or in an electronic equivalent as approved under § 803.14. You may obtain this

form and all other forms referenced in this section from any of the following:

(a) The Consolidated Forms and Publications Office, Beltsville Service Center, 6351 Ammendale Rd., Landover, MD 20705;

(b) FDA, MEDWATCH (HF-2), 5600 Fishers Lane, Rockville, MD 20857, 301-827-7240;

(c) Division of Small Manufacturers, International, and Consumer Assistance, Office of Communication, Education, and Radiation Programs, Center for Devices and Radiological Health (CDRH) (HFZ-220), 1350 Piccard Dr. Rockville, MD 20850, by e-mail: DSMICA@CDRH.FDA.GOV, or FAX: 240-276-3151;

(d) On the Internet at <http://www.fda.gov/medwatch/getforms.htm>.

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§ 803.12 Where and how do I submit reports and additional information?

(a) You must submit any written report or additional information required under this part to FDA, CDRH, Medical Device Reporting, P.O. Box 3002, Rockville, MD 20847-3002.

(b) You must specifically identify each report (e.g., “User Facility Report,” “Annual Report,” “Importer Report,” “Manufacturer Report,” “10-Day Report”).

(c) If an entity is confronted with a public health emergency, this can be brought to FDA’s attention by contacting the FDA Office of Emergency Operations (HFA-615), Office of Crisis Management, Office of the Commissioner, at 301-443-1240, followed by the submission of an e-mail to emergency.operations@fda.hhs.gov or a fax report to 301-827-3333.

(d) You may submit a voluntary telephone report to the MEDWATCH office at 800-FDA-1088. You may also obtain information regarding voluntary reporting from the MEDWATCH office at 800-FDA-1088. You may also find the voluntary MEDWATCH 3500 form and instructions to complete it at <http://www.fda.gov/medwatch/getforms.htm>.

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